Operating Instruction

Steam Sterilizer

A 35 - S

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1. Preliminary Notes

1.1 General Remarks

- This instruction manual provides the basis for the training of the operator and provides information, which is essential for the operation and functioning of this apparatus.

- It is appliance orientated and contains the apparatus description, handles the assembly, starting procedure, cleaning instructions, maintenance, and maintenance roster, including effectiveness test and repairs, as well as storage and transport requirements.

- This instruction manual contains important indications, which demand particular attention. These are marked "CAUTION", "ATTENTION" or "INDICATION".

  CAUTION!
  is used when work- or operating procedures have to be adhered by strictly, in order to avoid endangerment of personnel. This includes indications of special risks while handling the appliance.

  ATTENTION!
  refers to work- or operating procedures, which have to be followed precisely, in order to avoid damage to, or destruction of the apparatus. This also applies to routine work, which is performed after particular stresses or under unusual atmospheric influences or operating circumstances.

INDICATION, IMPORTANT:
addresses process related technical requirements, which demand particular attention from the appliance user.

The references to illustration and position numbers in the text are placed in brackets, i.e. (3/5) refers to illustration number 3, position number 5.

1.2 Safety Indications

This instruction manual provides information about a medical device which may cause danger by electrical voltage or current, mechanical, thermal or, if applicable, chemical processes, respectively. Physical injury or material and property damage may occur.

Therefore, following safety instructions are strongly recommended to be followed.

- The device shall be used only for its intended use as described by its designation and within this manual.

- The user shall follow strongly the advices and recommendations of this manual. Inappropriate use of the device may cause damage of the equipment or be harmful to the user.

- Please read carefully these operation instructions before starting installation or preparing operation.

- Preparatory procedures prior to operation shall be performed only by the user/operator according to this manual or by personnel specifically trained for this purpose.

- Be advised never to put the device into operation when it is damaged or seems to be damaged.

- Service and repair actions shall be done only by qualified trained persons considering

    - these Operating Instructions
    - all other applicable supplemental user instructions
    - applicable national laws and safety regulations

- Preservation of the maintenance schedule shall be ensured by the user. Maintenance and service actions shall be performed only by the manufacturer or by its authorized representatives. If maintenance actions will be performed by personnel of the user, he is responsible for the safety and maintenance indications to be followed.

2. Apparatus Description

Item Description	Part-No.:
A35-S	029949

Manufacturer:
Webeco Hygiene in Medizin
und Labor GmbH & Co. KG,
Mühlenstraße 38, 23611 Bad Schwartau

3. Area of Application

This Small-Steam-Sterilizer provides sterilization of wrapped or unwrapped surgical and dental instruments at 134°C as well as sterilization of thermolabile sensitive to heat materials at 121°C. It is designed for use at on-site locations.

4. Specifications

4.1 Installation and Connection Data

Dimensions (heightxwidthxdepth)	:	440x500x700mm
Installation Base (widthxdepth)	:	500x550mm
Chamber Dimensions (diam.xdepth):		250x380mm
Weight	:	ca. 45kg
Electrical Requirements	:	230V/50Hz/10A
IEC 536 Protection Class	:	I
Supply Connector for Cooling Water:		G ¾

4.2 Ambient Conditions

		Operation	Storage and Transportation
Temperature	:	15-35°C	5-50°C
Pressure	:	850-1100mbar	650-1150mbar
rel. Humidity	:	0-85% rel. humidity	0-65% rel. humidity

4.3 Technical Parameters

Production-No.	:	
Year of Delivery	:	

Sterilizer Pressure Chamber

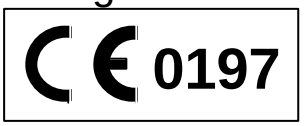
Permissible operation overpressure	:	3 bar
Test pressure	:	3,9 bar
Working Pressure	:	1,1 / 2,2 bar
Permissible operating Temperature	:	138 °C
Working Temperature	:	121 / 134 °C
Capacity of Sterilization Chamber	:	19,5 Liter
Heating System	:	electrical
Heating Capacity	:	2,0 kW
Acoustic Power Level	:	<85 dB(A)

4.4 Standards and CE-Conformity

According to the EEC Medical Device Directive (MDD) 93/42/EEC the small steam sterilizer WEBECO A 35 - S is a medical device and with reference to Annex IX of the MDD to be classified as class IIa medical device.

WEBECO GmbH & Co. KG has established a quality management system according to DIN EN ISO 9001 and DIN EN 46001 which has been approved by a "Notified Body" applying Annex II, article 3 of the MDD (reg. no. SY 9711455 01).

On this base the small steam sterilizer WEBECO A 35 - S has been applied to a regular procedure for evaluation of conformity and has been proved to be compliant with the essential requirements of Annex I of the MDD. This allows the sterilizer to be marked by the sign



A respective formal Declaration of Conformity has been duly signed.

Conformity of the sterilizer type A 35 - S in accordance with this instruction manual with the a.m. MDD 93/42/EEC also includes compliance with the essential requirements of the EEC-regulations as listed below:

- 73/23/EEC (Low Voltage Directive) in conjunction with 93/68/EEC
- 89/336/EEC (EMC-Directive) in conjunction with 92/31/EEC and 93/68/EEC

As far as applicable for a.m. directives the apparatus A 35 - S complies with the following standards:

- EN 61010-1
- EN 55011
- EN 50082-2
- EN 61010-2-041
- EN 50081-1
- applicable standards of the series DIN VDE 0100, in compliance with IEC 364

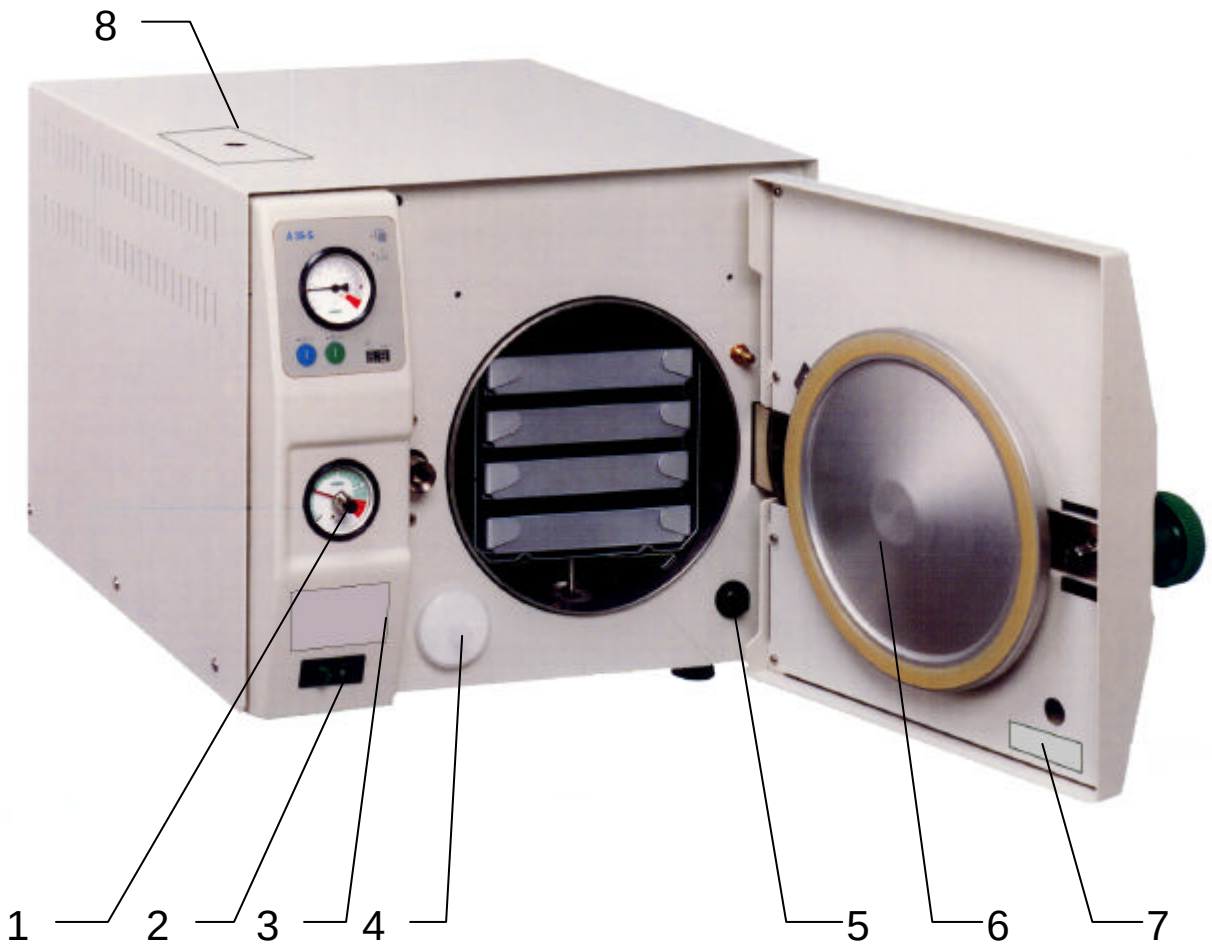
Furthermore this sterilizer complies with DIN 58 946, part 5, actually known requirements of the future European standards for small steam sterilizers, requirement level S (draft prEN 13060-1 and draft prEN 13060-4).

The apparatus contains a pressure chamber of "Test Group I" in compliance with §8 of the German Regulations for Pressure Vessels. We thus confirm, that pressure vessel and locking device are constructed in accordance with all applicable Technical Regulations for Pressure Vessels and AD-regulations, have been properly manufactured and submitted to a fluid pressure test. In addition, an acceptance test comprising a specification test and an equipment test has been administered by the quality assurance section.

Within the framework of a type test in accordance to the German Regulations for Pressure Vessels the register mark TÜV- DB 123/01 was formally issued.

5. Apparatus Overview

Illustration 1: WEBECO A 35 - S, Front View



1. Pressure gauge
2. Main Switch
3. Operation Quick Guide
4. Aeration Filter
5. Drainage Valve
6. Chamber Door
7. Apparatus Name Plate
8. Cover Feed Water Reservoir

5.1 Pressure Gauge (1/1)

With the black pointer of the pressure gauge the relevant/present chamber pressure is displayed.
The red drag pointer shows the highest pressure that has been reached during the program-run, if he has been reset to „0“ before the program-start.

green:	appropriate conditions
red :	inappropriate conditions
>0< :	door may be opened

5.2 Main Switch (1/2)

The main switch lightens green when it is switched on.

5.3. Aeration Filter (1/4)

Please pay attention to chapter 9.4 „Replace Aeration Filter“ when changing the filter.

5.4 Drainage Valve (1/5)

To drain the water reservoir put the draining hose onto the valve and open it by turning it left.

5.5 Chamber Door with Rotary Closing Device (1/6)

Please pay attention to chapter 9.4 „Replace Door Sealing“ and „Grease Spindle at the Rotary Closing Device“.

5.6 Apparatus Name Plate (1/7)

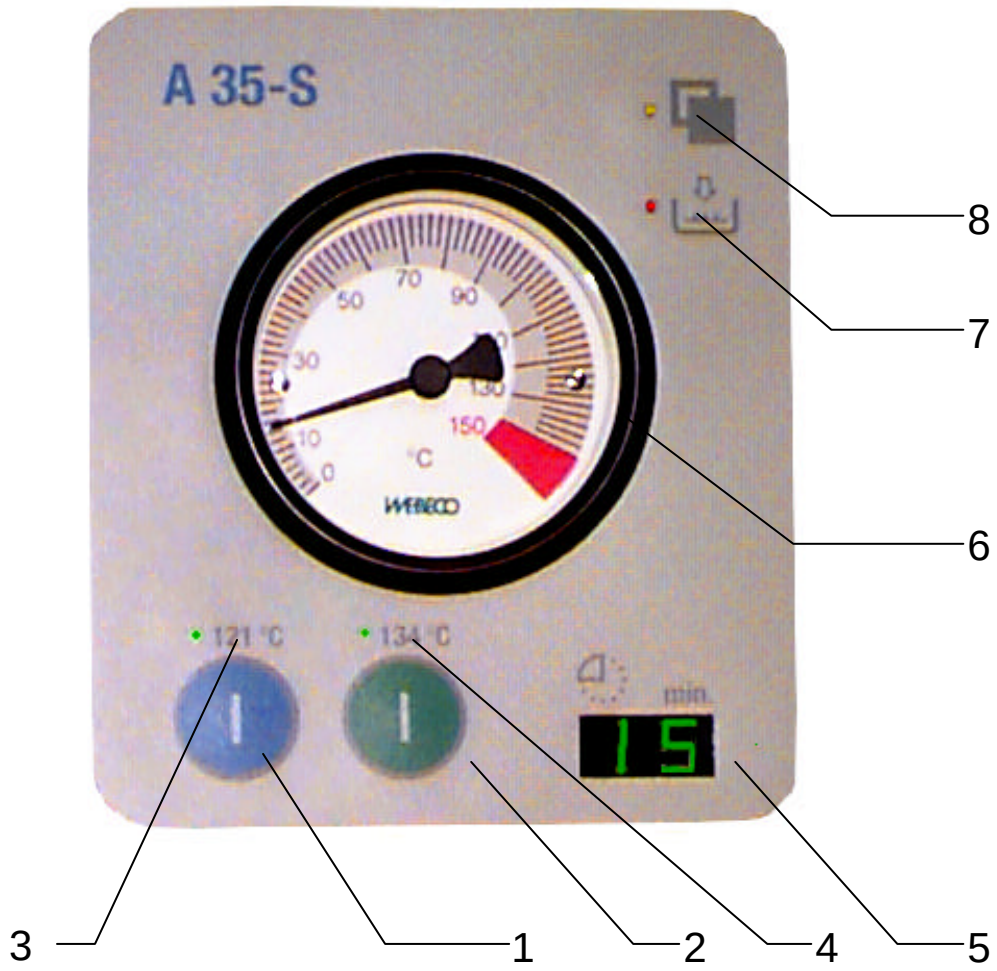
If there are any questions to the customer service please provide the production-No. which is indicated here.

5.7 Feed Water Reservoir (1/8)

When charging the feed water reservoir for the first time, 15L of demineralized or destilled water have to be filled in. If

the red display „Water Shortage“ is enlighted, please refill 5L demineralized or destilled water.

Illustration 2:
WEBECO A 35 - S, Display- and Operation Unit



1. Program Start 121 °C
2. Program Start 134°C
3. Program Indicator 121°C
4. Program Indicator 134°C
5. Display Residual Time
6. Thermometer
7. Display Water Shortage
8. Display Door unlocked

5.8 Program-Start-Key 121°C (2/1)
This key starts the program „Instruments Thermolabile 121°C“.

5.9 Program-Start-Key 134°C (2/2)
This key starts the program „Instruments General, 134°C“.

5.10 Program Indicator 121°C (2/3)
During the program-run the green display is enlighted. The end of the program is signalized by a flashing indication.

5.11 Program Indicator 134°C (2/4)
During the program-run the green display is enlighted. The end of the program is signalized by a flashing indication.

5.12 Display „Residual Time“ (2/5)
The residual time is shown in minutes from the program-start to the program-end.

5.13 Thermometer (2/6)
The Thermometer shows the actual temperature in the chamber.

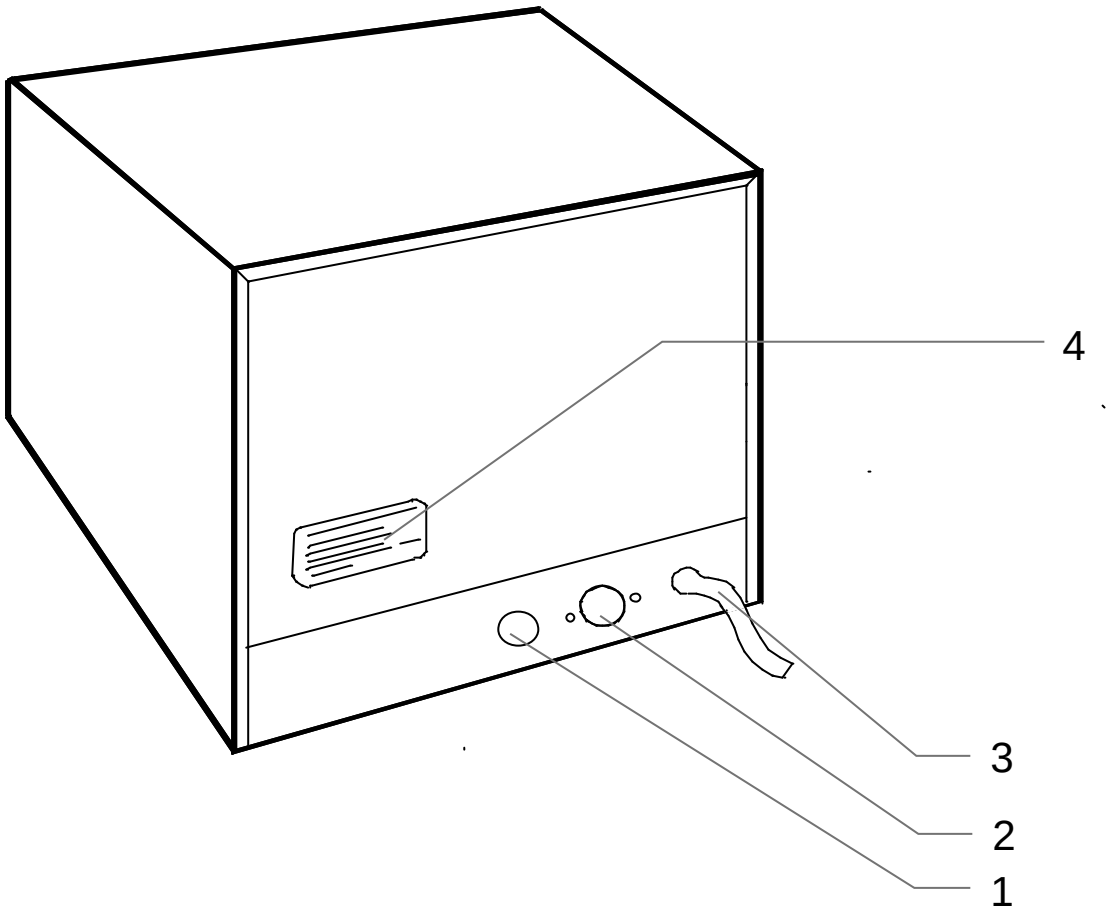
grey : appropriate conditions
red : inappropriate conditions

5.14 Display „Water Shortage Feed Water Reservoir“ (2/7)
Fill demineralized water or destilled water into the reservoir when the indication is red.
The device can not be started in this situation.

5.15 Display „Door unlocked“ (2/8)
The indication is shining yellow when the door-lock is unlocked. Please open the door only in this situation,

additional to this the indication chamber pressure has to show >0<.

Illustration 3: WEBECO A 35 - S, Rear View



1. Cool-water supply / condensate drainage, connector G ¾

2. Cool-water intake, connector G ¾

3. Electrical connecting cable with sealed contact plug

4. Manufacturer Name Plate

5.16 Cooling Water/Condensate Drainage (3/1)

Connect hose for shared outlet of condensate and - if necessary - cooling water here.

ATTENTION!

Do not use the optional salable condensate reservoir when using the A35 - S with supplemental cooling. Operating the apparatus with supplemental cooling requires the connection of the connection pipe (contained in supply schedule) to an outlet to be provided on-site (see chapter 7.1).

5.17 Cold Water Supply (3/2)

When using supplemental cooling (see chapter 7.7) connect pipe here as described in chapter 7.1.1.

6. System Functions

The WEBECO Small-Steam-Sterilizer A 35-S operates with streaming and saturated steam and functions according to the flow processing procedure.

The feed water which is required for the production of steam is filled in a feed water container.
This feed water container has to be filled with demineralized or deionized water (approx. 15 liters) after removing the cover of the housing.
From this container the required amount of feed water will be metered into the sterilization chamber automatically during the program run.

The chamber is designed so that the required steam is produced in the bottom part. Cooling water can be connected to the apparatus to shorten the program run up to 10-15% or when the apparatus is frequently used for example 3 times directly one after another.

The required dosage is automatically produced during the different phases.

The drying vacuum prevents from steam exhaust when the door is opened.

After loading the door is shut steamtight by turning the closing spindle. For the sterilization process the respective program will be selected and started.

The following programs may be selected:

Program 1 : General Program for Instruments 134°C
Program 2 : General Program for thermolabile Instruments 121°C

With program start, the sterilization cycle progresses as follows:

a) The sterilization chamber automatically fills with a metered amount of feed water.

b) The steam, created through heating up, displaces the remaining air from the chamber

c) The holding time phase commences when the operating pressure and thus the sterilization temperature, (provisions for saturated conditions), is reached.

d) At the end of the holding time, a decrease in pressure occurs and the drying phase begins, supported by physical vacuum.

e) The sterilization cycle is finished by ventilation of the sterilization chamber.
This is visually displayed by a flashing program indication (2/3;2/4). Before opening the door please ensure the pressure indicator (1/1) showing >0< bars.

Actual pressure- and temperature values can be monitored at the different instruments (1/1;2/6).

After starting the program cycle it cannot be interrupted. Interruption of the power supply (main switch 1/7) however, is followed by a program break. After power coming back, a failure recovery program automatically is activated (see also chapter 7.4), which leads to a safe system condition by which the sterilization goods can be unloaded without risk of hazard, however not sterile . The door can not be opened before this process (see chapter 7.5) !

CAUTION!

When loading or unloading the chamber, the door plate and the chamber walls are preheated. Do not touch these areas!

Danger of burning!

ATTENTION!

Proper and safe sterilization requires an immaculate water quality for the steam-generator. Use only demineralized water or aqua. dest.!

INDICATION:
As the connection hose (3/2) is under full pressure of the water supply whenever the inflow of the cooling water is automatically interrupted, the intake line should be regularly checked to ensure its proper condition, (no tears, proper connections)!

Optionally a water-stop-device (part-no.: 02 41 73) can be provided to be set between the raw water valve and the connecting hose to the sterilizer (see also chapter 10). This is to avoid severe water damage due to burst hoses.

IMPORTANT:
After completion of the last sterilization process of the day the apparatus and - if cooling water is used - the water are to be turned off.

7. Installation and Operation

7.1 Installation

The installation of the apparatus should be performed by two persons who grip lateral under the apparatus for carrying.
The location for the A 35-S may be freely chosen. The location of the device has to provide a horizontal surface.

To avoid infringement of the device by heat stagnation, care should be taken for free ventilation of cooling air for access below the bottom plate and escape from the top of the back plate, when emplacing the unit.

The apparatus is specially designed to ensure a steam-free working environment. A Drainage-steam-line is not necessary. If cooling-water is used, however the chosen location must be able to facilitate a cooling water intake and drainage-pipe connection with the apparatus.

For the working of the device without the supplemental cooling water intake a condensate container is available (part-no. 03 01 53). It is used for the condensate which obtains during the sterilization process.

7.1.1 Water Supply

With regard to the water supply, the provisions of the DVGW in accordance with DIN 1988, part 4, (Technical Regulations for Drink-Water Installations), are to be followed.

a) Cooling Water Inflow (3/2)

The cooling water delivery pipe (hose with a connector on both sides G3/4) is connected to the cooling water inflow (3/2) and the on-site G ¾ water valve. The cooling water inflow is provided with a hinged cover which is to be removed from the cooling water delivery pipe before it is connected. The hinged cover should be stored at a secure place.

In the case of equipment failure, the back-flow of processed water, (used drinking water), into the drink-water system is to be prevented by a back-flow prevention device, either as single safety system at the apparatus supply or via a collective safety device system for the work area, (department, practice, etc.).

As single safety system, a back-flow prevention device with pipe ventilation, which screws directly onto the water valve G 3/4, may be supplied, (article no. 5 1630 0120), (to be installed at the wall). Please note, that the water valve must be situated at least 150 mm above the apparatus supply, (see chapter 10).

IMPORTANT:

When deinstalling the Water Cooling the cooling water inflow has to be tightened with the lock again. Otherwise water leakage is possible.

b) Cooling Water and Condensate drain (3/1)

Working with an existing drain or with an additional cooling the drain line (hose with one connector G3/4) is connected at the cooling water and condensate drain (3/1) and a drain on the part of the builder.
Working without an additional cooling and if no drain is existing on-site the drain line is connected with an optional deliverable condensate reservoir (article no. 03 01 53). The water level is to be inspected before every start of the program. A filled up reservoir has to be changed at once, otherwise the condensate reservoir might overflow.

The drainage pipe is to be installed as free drainage (analogue dish washing machine drain or freely (> 20mm) ending above gully). This drain must be suited lower than the bottom of the apparatus. Care should be taken to arrange the drainage hose such that no water backwash occurs.

IMPORTANT:
The working of the apparatus with the condensate reservoir is only possible without the supplemental cooling. If this is not considered the condensate reservoir is overflowing.

c) Connecting Pipes

Suitable connecting pipes for supply and drainage of cooling water resp. condensate are included in the delivery.

7.1.2 Electric Supplies

The sterilizer may be connected to a fixed socket with sealed contact for alternating voltage.

Electrical power
2,1 kW at 230 V AC - 50Hz

7.2 Operation

7.2.1 Operating Prerequisites

- Ensure, that the apparatus plug is inserted into the socket.

- Ensure, that the water hoses are properly connected.

- Switch on mains

- Open the water line if supplemental cooling is connected

- Turn the red drag pointer of the pressure gauge left to „0“.

- Open door

7.2.2 Operating Procedure

7.2.2.1 Loading the Sterilizer

The sterilization material is loaded into the chamber in sterilizing baskets, trays or dishes. Unwrapped solid material (no hollow materials) may be sterilized up to a weight of max. 3kg. Solid material wrapped in appropriate sterilization load wrapping may be sterilized up to 1kg max. See details in chapter 7.223 to 7.225.

WEBECO offers containers, suitable for this sterilizer, made from aluminium, or baskets made from stainless steel (see accessories list).

ATTENTION!
When loading or unloading the chamber the door plate and the chamber walls are preheated. Do not touch these areas! **Danger of burning!**

INDICATION:
The height of the wrapped and unwrapped sterilization load is to be limited, so that the minimal distance to the upper edge of the loading equipment or inside of the lid or stack (basket on basket or bowl on bowl), is at least 2cm.

Instruments in sterilization wrappings (e. g. Transparent Foil/Paper wrapping) are to be placed in aluminium dishes flatly on the paper-side of the wrapping. The wrappings may not be placed on top of each other res. they may not overlap. Items with areas on which condensate may be produced are to be arranged so that accumulating condensate may drain out.

After loading the door is to be shut. Give the closing spindle a firm turn clockwise. Closing of the door is monitored by a door contact switch.

ATTENTION!
The sterilization of liquids i. e. warmth-volatile materials is not permitted. Danger of explosion!

7.2.2.2 Cleaning of the Sterilization Material prior to Sterilization

In order to comply with the requirements of sterilization load maintenance, proper cleaning of sterilization materials is absolutely essential. The cleaning of instruments, glassware, pipettes, etc., is also essential to avoid that oil- and protein containing contaminants burn in and thereby discolour instruments and sterilizer (Scalding).

Proper cleaning is possible, if the instruments are soaked in water, which contains fat- and protein dissolving substances, for ca. 30 minutes. This is then followed by thorough rinsing and drying of the instruments. In addition to the removal of contaminants, special care is to be taken that wash-active substances (WAS) are removed. For the last rinsing act demineralized water or destilled water shall be used!

The sterilization material then is to be dried.

If oil treatment is recommended by the manufacturer prior to sterilization, only emulgating special instrument oil may be used for the treatment of the sterilization material.

To avoid that oil and other contaminants from the sterilization goods drip into the dosing container, a water separation system has been arranged in the apparatus, i. e. contaminated condensate will be wasted.

7.2.2.3 Wrapping and Loading of Sterilization Load

For wrapping sterilization goods and sterilization load supply, bags made from sterilization paper according to DIN 58 953, part 3, or from transparent sterilization wrapping, (paper and foil), according to DIN 58 953, part 4, are to be used.
The seal seams should have a minimal width of at least 6 mm; double seams are recommended. Between seam and sterilization load there should be a free gap of at least 30 mm.

Alternatively the sterilization goods may be sterilized unwrapped in sterilization containers.

Using paper as sterilization wrapping keep in mind DIN 58953, part 2.

The maximum load for massive wrapped instruments is 1.0 kg.
Instruments in sterilization wrappings are to be placed in aluminium dishes flatly on the paper-side of the wrapping. The wrappings may not be placed on top of each other resp. they may not overlap. Items with areas on which condensate may be produced are to be arranged so that accumulating condensate may drain out.
The load has to be distributed equal on different sterilization trays if there is a great volume of massive wrapped sterilization goods.

ATTENTION!
Plastic bags or tubes are not suitable for sterilization wrapping and should be avoided at all cost, i.e. only used as storage wrapping at a later stage.

The sterilizer A 35 - S is supplied complete with an insert tray with removable bearing rails for holding dishes and trays. When loading a basket, the tray is removed.

IMPORTANT:
For an optimal drying transparent-sterilization wrapping is recommended (paper and foil) according to DIN 58 953 in relation with dishes made of aluminium. When using other wrappings res. other materials (plastics, stainless steel) the drying of the sterilization goods is significantly reduced so that additional drying times (e. g. 5-10 minutes evaporation with slightly opened door) are recommended.

ATTENTION!
Cellulose- and cotton surfaces are not suitable!

7.2.2.4 Post-Treatment of Sterilization Material

When unloaded from the sterilizer, all material sterilized with steam contains residual moisture, which should evaporate freely when the material is cooled.

Compared to containers made from aluminium or wire baskets, the conditions for stainless steel and chromium plated brass are particularly unfavourable.

Overloading the sterilizer has negative consequences for the drying result.
Passing the commended times of sterilization without additional cooling the drying of the sterilization goods is significantly reduced so that additional drying times (e. g. 5-10 minutes evaporation with slightly opened door) are recommended (see chapter 6).

INDICATION:
If dishes or trays are used, they should not be set onto flat and solid surfaces. The condensate coat created by cooling down to room temperature may subsequently cause soaking of the wrapped sterilization material. Therefore, dishes and trays are better set on grids or other structured surfaces.

CAUTION!
When loading or unloading the chamber, the door plate and the chamber walls are preheated. Do not touch these areas!
Danger of burning!

7.3 Programs

7.3.1 Program Selection/Start

According to the nature of the sterilization load, the following programs may be selected.

Program 1	:	General Program for Instruments 134°C
Program 2	:	General Program for thermolabile Instruments 121°C

The programs will be started with the respective program start-key. During operation the running program is indicated by the respective green display (2/3;2/4). At the same time the door spindle will be locked automatically, that means the door can not be opened yet (see also chapter 7.5).

IMPORTANT:
The sterilization chamber is pre-heated very much after a program run at 134°C. At a directly following program run of thermolabile instruments (121°C) the good might be damaged. Please wait at least 10 minutes for cooling down leaving the chamber door open.

7.3.2 General Program for Instruments 134°C

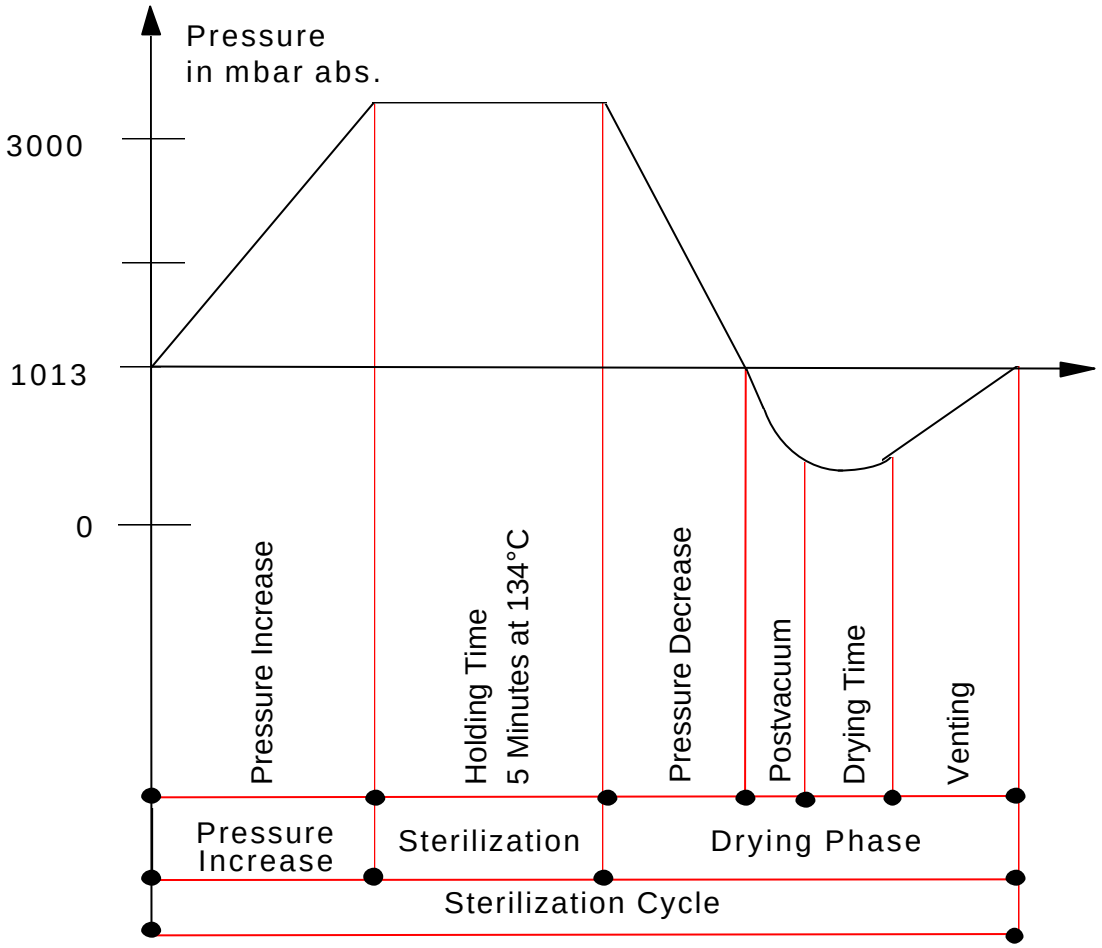
This program is designed for sterilization of wrapped (see chapter 7.2.2.3) or unwrapped solid sterilization material (no narrow-lumen hollow objects). The sterilization time is 5 minutes.

ATTENTION!

The net loading weight (sterilization goods without baskets, containers etc.) is given for:

Instruments unwrapped	Instruments wrapped
max. 3,0kg	max. 1,0kg

This program will proceed as depicted in the following line graphic:


Pressure
in mbar abs.
3000
1013
0
Pressure Increase
Holding Time
5 Minutes at 134°C
Pressure Decrease
Postvacuum
Drying Time
Venting
Pressure
Increase
Sterilization
Drying Phase
Sterilization Cycle

7.3.3 General Program for thermolabile Instruments 121°C

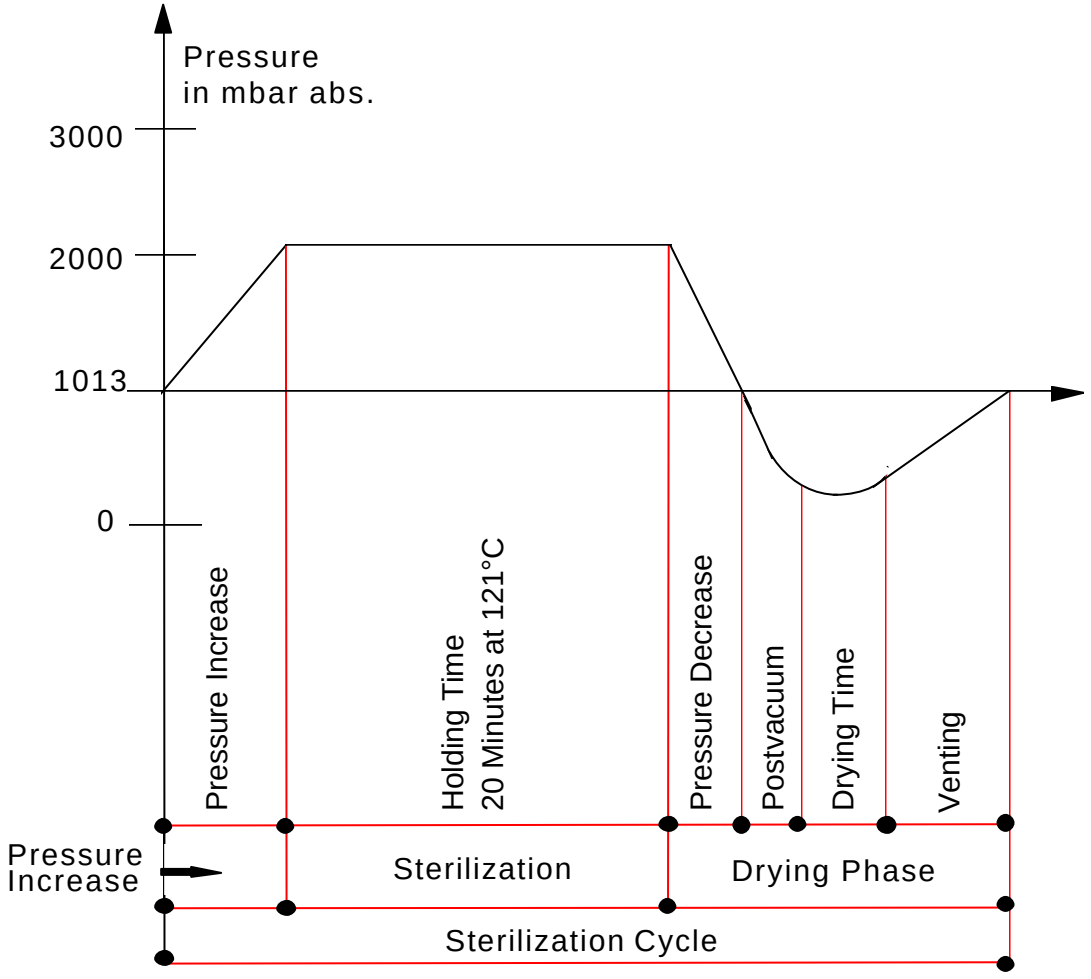
This program is designed for the Sterilization of wrapped or unwrapped thermolabile solid sterilization material (no narrow-lumen hollow objects). The sterilization time is 20 minutes.

ATTENTION!

The net loading weight (sterilization goods without baskets, containers etc.) is given for:

Instruments unwrapped	Instruments wrapped
max. 3,0kg	max. 1,0kg

This program will proceed as depicted in the following line graphic:



7.4 Notification- and Failure Reports

Functions and operating conditions of the sterilizer are continuously controlled by the internal computer control.
In case of malfunctions or deviations an alarmcode is displayed in the residual time display.

7.4.1 Indications

Text in Display		**Cause**	**Countermeasures**
A1	pressure switch defective	cable break pressure switch defective	Notify customer service
A2	Pressure Increase too long	Water Shortage Untightness Heating defect	Refill Water Notify customer service Notify customer service
A3	Exceeding reswitching time of Heating Element	Water Shortage unsuitable Loading Too much Loading	Refill Water see Operating Instruction chapter 7.2.2 Reduce Loading
A4	Failure Power Supply	Failure of Power Supply	Test Power Supply existing supply voltage notify customer service

ATTENTION!
If failures are indicated and the cause can not be rectified, the appropriate customer service is to be informed.

CAUTION!
If a program ends with a failure, the sterilization material is considered to be non-sterile.

After a failure hot water may stand in the chamber and rinse out when opening the door.

Danger of burning!

IMPORTANT:
If failures occur during the process, a recovery program will run automatically, so that the device is in a predetermined and safe operation condition and that the apparatus door may safely be opened.

7.5 Automatic Safety Lock

To ensure the safety of the operator, the sterilizer chamber is automatically secured by a door locking mechanism. The condition of this mechanism is indicated by the yellow display (2/8).

7.5.1 Door Spindle Interlock

At the start of a program cycle (pushing the „Start“ button(2/1; 2/2)), the door spindle is locked automatically. In this condition, the door spindle may only be turned one quarter rotation counter clockwise, until the mechanism locks.

The door spindle is not allowed to be tightened up or further to be closed during the running program.

7.5.2 Unlocking of Door Spindle

When switching on the sterilizer or at end of one program the door interlock device system is released and the door may be opened. This condition is indicated by the shining of the yellow display (2/8).

INDICATION:
If an attempt to open the door has been made while a sterilization process was in progress, please take note of the following:

1. After correct program run „Program End“ release the locking device mechanism by applying a slight turn.

2. The door locking device system can then be opened as usual, by turning the spindle counter clockwise.

7.5.3 Opening the Door during Power Failure

During power failure the door can not be opened because of the automatic safety lock. An emergency unlocking may only be performed by the customer service or technical trained personnel.

7.6 Shutdown of Apparatus

7.6.1 Temporary Standstill

After the final sterilization of the day:

- Interrupt cooling water supply -if water cooling is installed - through closing of water tap
- Switch off power supply (1/2)

7.6.2 Shutdown of apparatus for standstill or transport (longer standstill, a few weeks)

- Pull out plug
- If necessary disassemble connecting water pipes (3/1;3/2) and remove remaining water. Close water inlet with lock (3/2).
- Turn open drainage valve (1/5) and thoroughly empty feed water reservoir.
- Wipe out chamber with dry cloth.
- If necessary clean insert tray, instrument dishes and lift, and store in chamber
- Close chamber door (1/6) without applying contact pressure, for transport close chamber with applying contact pressure.
- Pack apparatus and connection pipes

7.7 Activating/Deactivating Additional Cooling

The setup-procedure informs the apparatus if cooling-water is connected as a supplemental cooling or not.
At every change of the method of operation the setup procedure has to be carried through.

The set-up procedure is initialized if the left key (2/1) is pressed when switching on the main switch (1/2). As confirmation „c“ is shown in the display of the residual time. After releasing the key „00“ or „01“ is shown.

The meaning of the numbers is as follows:

00 : additional cooling off
01 : additional cooling on

When using the right key it is possible to switch between „0“ and „1“. Additional using of the left key (2/1) confirms the choice.

After releasing of the key the apparatus is in its normal operating condition. The A 35-S can work in continuos operation with or without supplemental cooling. Thus the process-time is shortened by approx. 10-15%.

When working without supplemental cooling after 3 sterilizations directly after one another a reduced drying capacity or steam disturbance from the water reservoir is possible.

IMPORTANT:
Operation with supplemental cooling without water supply leads to highly reduced drying capacity.

8. Effectiveness Test

8.1 General

The effectiveness of the sterilization process of Automat A35 - S to be tested with:

- thermoelectric measurements and/or
- biological indicators according to DIN EN 866-3

The test is based on:

- DIN 58 946, part 8; Steam Sterilizers, Small Sterilizers, Effectiveness Test

According to this standard the following tests are to be conducted:

- operation procedure test prior to first use, i.e. when acquiring the apparatus

- periodical tests in six months intervals

- special test to detect necessary repairs or replacement of spare parts which might influence sterilization performance

- special test, when unsatisfactory sterilization performance is suspected

IMPORTANT:
The tests and their results are to be documented

8.2 Biological Test

The two sterilization programs of the A35-S are to be tested. The test is to be conducted with biological indicators according to DIN EN 866-3, part-no. 00 92 92. For this test, sterilization material and sterilization wrapping appropriate for respective purpose of the sterilization program is to be used. The biological test of the A 35 - S is to be conducted in accordance with DIN 58 946, part 8.

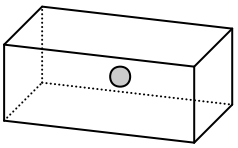
For the biological test 1 to 5 bio-indicators are needed for each container or dish dependent of the groth of the sterilization-container respectively of the groth of the dish with perforated bottom.

Additional to this one bio-indicator is needed. This additional bio-indicator is the positive-control. This indicator is not subjected to the tested method. The indicator is not put into the sterilizer it is <u>not</u> treated.

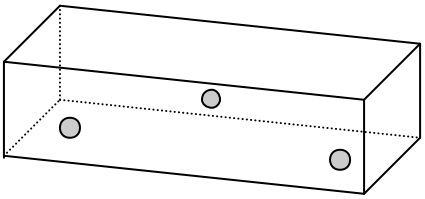
volume of basket-/container in liter	floor space of the sterilization-dish in cm2	quantity of bio-indicators
< 1	< 200	1
1-5	> 200	3
> 5	-	5

The bio-indicators are placed in the load of the small-steam-sterilizer at the critical place for the process (see picture).

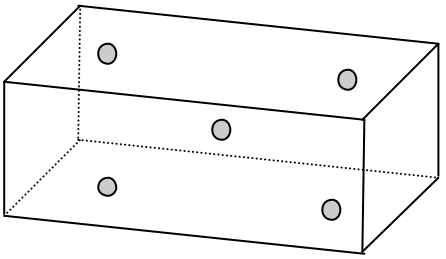
Arrangement of one bio-indicator
in the sterilization-good



Distribution of 3 bio-indicators
in the sterilization-good



Distribution of 5 bio-
indicators in the sterilization-



The indicators remain in their primary-packing (paper). The indicators have to remain in their packing even after the sterilization process to prevent a recontamination.

They have to be send in their packing to the WEBECO-customer service or an independent hygienic-institute. There the used bio-indicators are fertilized and tested if micro-organism grow. The untreated bio-indicator is fertilized as well and has to show groth.

9. Maintenance Work

9.1 General

To ensure continued and proper use of the apparatus, regular cleaning and maintenance work is required. This is to be conducted by the operator/user or person in charge of the equipment.

Repairs on the apparatus are to be conducted by the manufacturer, WEBECO GmbH & Co. KG, or authorized customer service only!

In addition, we refer to the operator requirements in accordance with DIN 58 946, part 5, attachment A 4, (repeat tests), and A 5, (special tests).

ATTENTION!
The apparatus is not explosion protected, therefore the apparatus may not be treated with cleaning or desinfection agency which with air could generate an explosive mixture.

9.2 Maintenance

Nr.	Test Location/Name	Test or Activity	Reference	Times to be performed
1	Chamber floor insert tray instrument dishes Wire sieve inside discharge pipe	cleaning - by user/person in charge of equipment	according to chapter 9.3	weekly and if required
2	Spindle at rotary closing device	greasing - by user/person in charge of equip-ment	according to chapter 9.4	weekly
3	Reservoir	cleaning - by user/person in charge of equipment	according to chapter 9.4	if required, every three months
4	Ventilation filter	replacing - by user or customer service	according to chapter 9.5	every 6 months and if required
5	Entire apparatus	safety test - by manufacturer or customer service	according to chapter 9.1	if required, every year
6	Chamber door	replacing of seal - by user/person in charge of equipment or customer service	according to chapter 9.5	if required, every 2 years
7	Entire apparatus	complete overhaul - by manufacturer or customer service		every 5 years

9.3 Cleaning

Wipe out chamber with moist cloth and dry. Clean insert tray and instrument dishes with a wetting agent, rinse off with clean water and dry.

9.4 Repairs

1. Empty the clean water reservoir (1/5) by turning the drainage valve.
   If the reservoir contains residue, it is to be cleaned prior to the new fill.
   Depending on residue, a cleaning- or fat-dissolving agent is to be used, which then is to be thoroughly rinsed off.

   CAUTION!
   Disconnect power supply prior to cleaning!

2. Grease spindle at the rotary closing device.

   Remove old fat rests from the spindle, then grease spindle with high melting point grease.

3. Replace aeration filter

- Switch on the unit and open the door.
- Remove filter and replace with new filter part-no. 02 31 79

  Close the door and switch off the unit again.

4. Replace door seal

- Switch on the unit and open the door.
- Remove door seal from the groove on the inside of the door.

  ATTENTION!
  Be careful not to damage the inside of the door and of the seal groove.

- Insert new door seal into groove and apply slight pressure to the door with the closing spindle.
- Switch off the unit again.

  ATTENTION!
- Lubricants may not be used.

10. Spare Parts, Accessories

The following spare parts and accessories are available from the manufacturer or an authorized customer service:

Article:	No. old:	No. new:
Aeration Filter	5 2014 0604	02 31 79
Drainage hose reservoir	2 0120 0106	01 21 69
Delivery hose G3/4“	5 6110 0006	02 51 49
Supply hose G3/4“-G3/4“	5 6110 0007	02 51 50
Insert Tray 2 or 4 Parts	1 0901 3518	00 16 85
Removal lever for Traydish	1 1112 4920	00 15 93
Removal lever standard	1 1112 4750	00 15 89
Door Seal	5 5405 3502	02 48 47
Instrument Dish, aluminium 35x18x3cm	1 0901 3518	00 11 63
Sterilization Container, aluminium 35x18x5cm	1 1109 6481	00 14 69
Sterilization Container, aluminium 35x18x18cm	1 0935 1818	00 11 93
Sterilization Basket stainless steel 35x18x8cm	1 5904 3501	00 92 32
Sterilization Basket stainless steel 35x18x18cm	1 5904 3502	00 92 33
Tray dish, aluminium 28x19x4cm	1 5928 1904	00 92 74
Tray dish, aluminium 28 x 19 x 3 cm	1 5901 2819	00 92 25
Back Flow Prevention	5 1630 0120	02 29 39
Water Stop Device	5 4107 0200	02 41 73

Condensate Reservoir	-	03 01 53
Biological Indicator (one item)	1 6002 1310	00 92 92

11. Operation Quick Guide

1. The water container has to be filled with demineralized or destilled water. Switch on mains.

2. Load sterilizer, (see chapter 7.2.2.1).
   Please see chapter 7.3 for loading instructions.

3. Close door and firmly turn closing spindle clockwise.

4. Turn the red drag pointer of the pressure gauge (1/1) left until „0“ is displayed.

5. Start suitable program according to kind of load to be sterilized by pressing the program-start-key (2/1;2/2).
   The running sterilization-cycle is shown through the program-display (2/3;2/4) above the „Start“ key.

6. After the start of the sterilization-cycle the residual-time-display (2/5) shows the remaining time until the „Program End“.

7. The end of the program is indicated by a blinking program-display (2/3;2/4).
   The sterilization material may be unloaded.
   While pressure reading >0< (black pointer) it has to be tested, if the necessary sterilization pressure 1,1 bars - 121°C, 2,1 bars - 134°C, has been reached.
   Otherwise the sterilization load must always be considered non-sterile.

8. Turn the closing spindle counter clockwise for opening of the door (see chapter 7.5).

9. Turn off apparatus after unloading it. Opening of the door after switching off power supply is not possible (see chapter 7.5).

10. Attention! Indication messages need attention, although the sterilization load may be used.

    When failures occur, the sterilization load must always considered non-sterile.
    Wait always until complete automated failure recovery cycle has passed.
    If necessary, notify the customer service.

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